US009456834B2

(12) **United States Patent**
Folk

(10) **Patent No.: US 9,456,834 B2**
(45) **Date of Patent: Oct. 4, 2016**

(54) **THROMBECTOMY DEVICE WITH DISTAL PROTECTION**

(71) Applicant: **COVIDIEN LP**, Mansfield, MA (US)

(72) Inventor: **Chris Folk**, Los Angeles, CA (US)

(73) Assignee: **Covidien LP**, Mansfield, MA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 663 days.

(21) Appl. No.: **13/664,802**

(22) Filed: **Oct. 31, 2012**

(65) **Prior Publication Data**

US 2014/0121672 A1 May 1, 2014

(51) **Int. Cl.**

A61B 17/221	(2006.01)
A61F 2/01	(2006.01)
A61F 2/915	(2013.01)
A61B 17/22	(2006.01)

(52) **U.S. Cl.**

CPC ***A61B 17/221*** (2013.01); ***A61F 2/013*** (2013.01); *A61B 2017/2212* (2013.01); *A61B 2017/22034* (2013.01); *A61F 2002/016* (2013.01); *A61F 2002/018* (2013.01); *A61F 2002/91558* (2013.01)

(58) **Field of Classification Search**

CPC A61B 17/221; A61B 2017/2212; A61B 2002/016; A61B 2002/018

See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

5,749,880	A	5/1998	Banas et al.
5,800,519	A	9/1998	Sandock
5,827,324	A	10/1998	Cassell et al.
5,941,896	A	8/1999	Kerr
5,947,995	A	9/1999	Samuels
6,231,598	B1	5/2001	Berry et al.
6,254,628	B1	7/2001	Wallace et al.
6,258,115	B1	7/2001	Dubrul
6,402,771	B1	6/2002	Palmer et al.
6,458,139	B1	10/2002	Palmer et al.
6,558,405	B1	5/2003	McInnes
6,991,641	B2	1/2006	Diaz et al.
7,041,116	B2	5/2006	Goto et al.
7,261,727	B2	8/2007	Thielen

(Continued)

FOREIGN PATENT DOCUMENTS

CN	1308508	A	8/2001
CN	1663536	A	9/2005

(Continued)

OTHER PUBLICATIONS

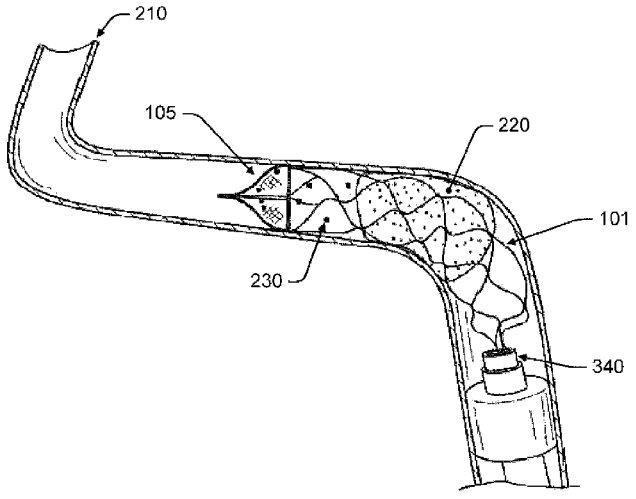
U.S. Appl. No. 13/950,930, filed Jul. 25, 2013.

Primary Examiner — Thomas McEvoy
(74) *Attorney, Agent, or Firm* — Mark J. Kertz, Esq.

(57) **ABSTRACT**

A vascular device is provided that includes a frame attached to a distal end of a delivery wire. The frame includes a cylindrical body formed of a plurality of interconnecting members, the interconnecting members being configured to exert a first radial force against an inner wall of an anatomical lumen. The vascular device further includes a protector having a proximal end, a distal end, and a profile that tapers distally from a proximal cross-sectional dimension to a reduced distal cross-sectional dimension. The protector is coupled to a distal end of the frame via a plurality of connecting members, each of the members extending from a distal end of a corresponding interconnecting member and converging distally to form a taper. The connecting members are configured to exert a second radial force, less than the first radial force, against the inner wall of the lumen.

24 Claims, 8 Drawing Sheets



(56) **References Cited**

U.S. PATENT DOCUMENTS

7,344,549	B2	3/2008	Boyle et al.	
7,344,550	B2	3/2008	Carrison et al.	
7,749,243	B2	7/2010	Phung et al.	
8,029,530	B2	10/2011	Gesswein et al.	
2001/0025195	A1	9/2001	Shaolian et al.	
2002/0004667	A1	1/2002	Adams et al.	
2003/0004536	A1	1/2003	Boylan et al.	
2003/0004541	A1	1/2003	Linder et al.	
2003/0074050	A1	4/2003	Kerr	
2003/0195554	A1	10/2003	Shen et al.	
2004/0006370	A1	1/2004	Tsugita	
2004/0039412	A1	2/2004	Isshiki et al.	
2004/0088000	A1	5/2004	Muller	
2004/0153117	A1	8/2004	Clubb et al.	
2004/0167568	A1*	8/2004	Boyle	A61F 2/013 606/200
2004/0193208	A1	9/2004	Talpade et al.	
2005/0038447	A1	2/2005	Huffmaster	
2005/0055047	A1	3/2005	Greenhalgh	
2005/0131449	A1	6/2005	Salahieh et al.	
2005/0209678	A1	9/2005	Henkes et al.	
2005/0283166	A1	12/2005	Greenhalgh	
2006/0122643	A1	6/2006	Wasicek	
2006/0282116	A1	12/2006	Lowe et al.	
2007/0060945	A1	3/2007	Gilson et al.	
2007/0208367	A1	9/2007	Fiorella et al.	
2007/0219579	A1	9/2007	Paul	
2007/0288054	A1	12/2007	Tanaka et al.	
2008/0091231	A1	4/2008	Boyle et al.	
2008/0208245	A1	8/2008	Hoffman	
2009/0105722	A1	4/2009	Fulkerson et al.	
2009/0240213	A1	9/2009	Miyagawa et al.	
2009/0240238	A1	9/2009	Grodrian et al.	
2010/0016946	A1	1/2010	McDermott	
2010/0087908	A1	4/2010	Hilaire et al.	
2010/0106178	A1*	4/2010	Obermiller et al.	606/194
2010/0168786	A1	7/2010	Dower	
2010/0268264	A1	10/2010	Bonnette et al.	
2011/0060212	A1	3/2011	Slee et al.	
2011/0257675	A1	10/2011	Mackiewicz	
2011/0295304	A1	12/2011	Jonsson	
2012/0022634	A1	1/2012	Kusleika et al.	
2012/0035650	A1	2/2012	Linder et al.	
2012/0083868	A1	4/2012	Shrivastava et al.	
2012/0245671	A1	9/2012	Wainwright et al.	
2012/0265238	A1	10/2012	Hopkins et al.	
2012/0330346	A1	12/2012	Frimerman	
2013/0345739	A1*	12/2013	Brady et al.	606/200
2014/0088634	A1	3/2014	Sanati	

FOREIGN PATENT DOCUMENTS

CN	101147705	A	3/2008
CN	101616639	A	12/2009
WO	WO-99/44542	A2	9/1999
WO	WO-2012/120490	A2	9/2012

* cited by examiner

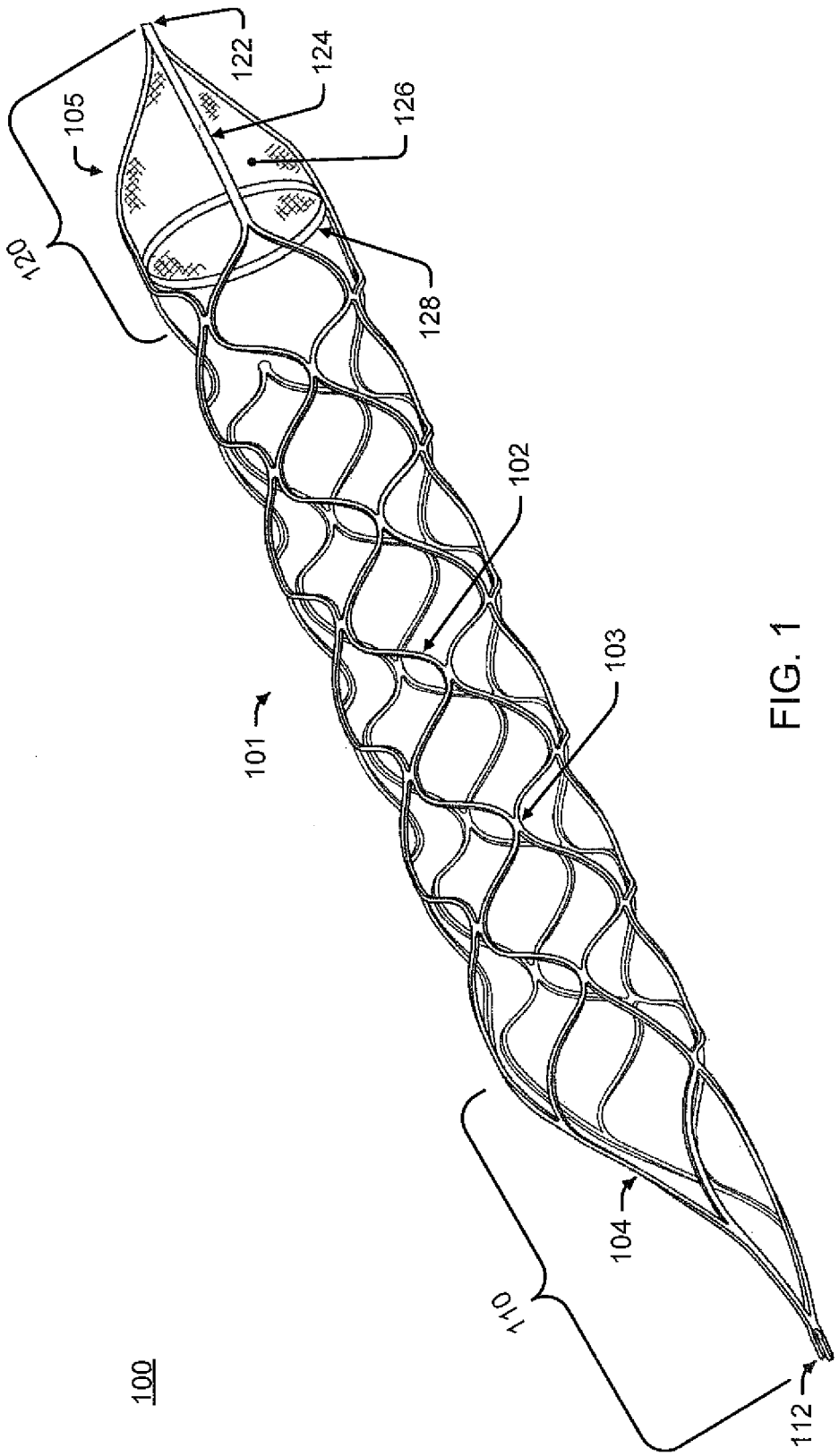


FIG. 1

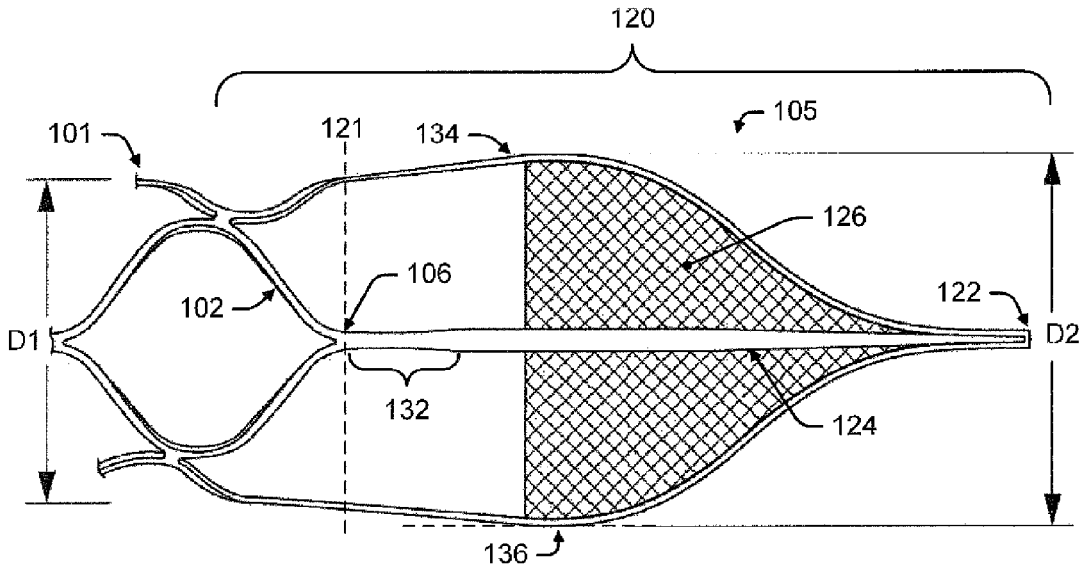

120
105
101
121
134
126
106
122
102
D1
D2
132
124
136

FIG. 2A

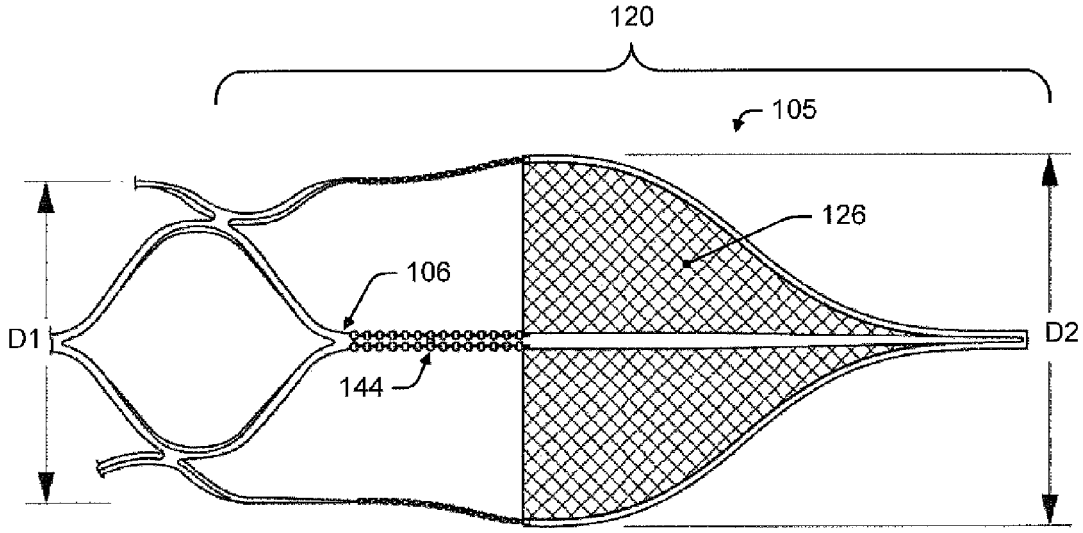

120
105
126
106
D1
D2
144

FIG. 2B

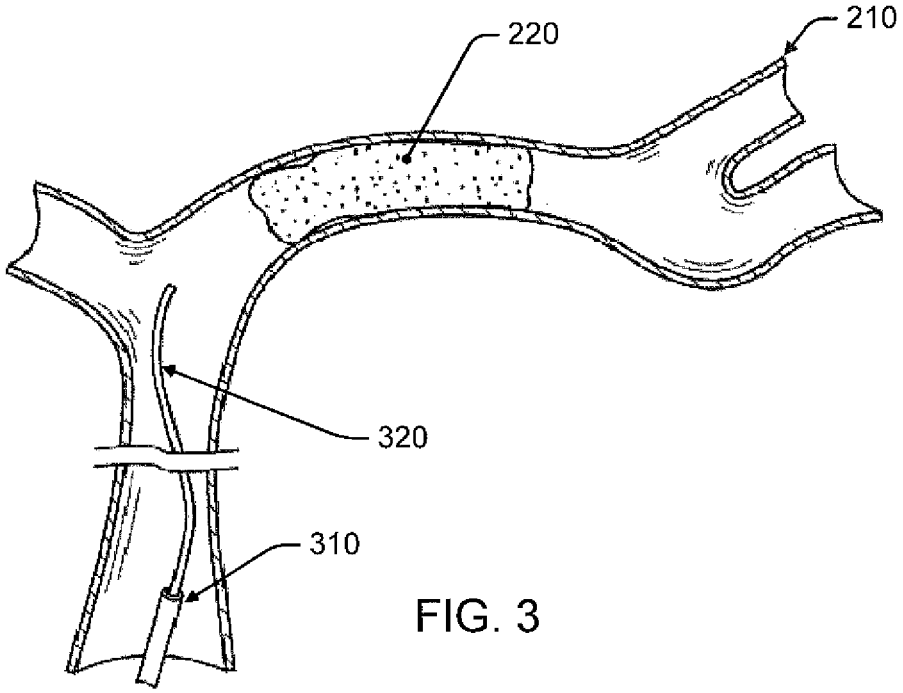


FIG. 3

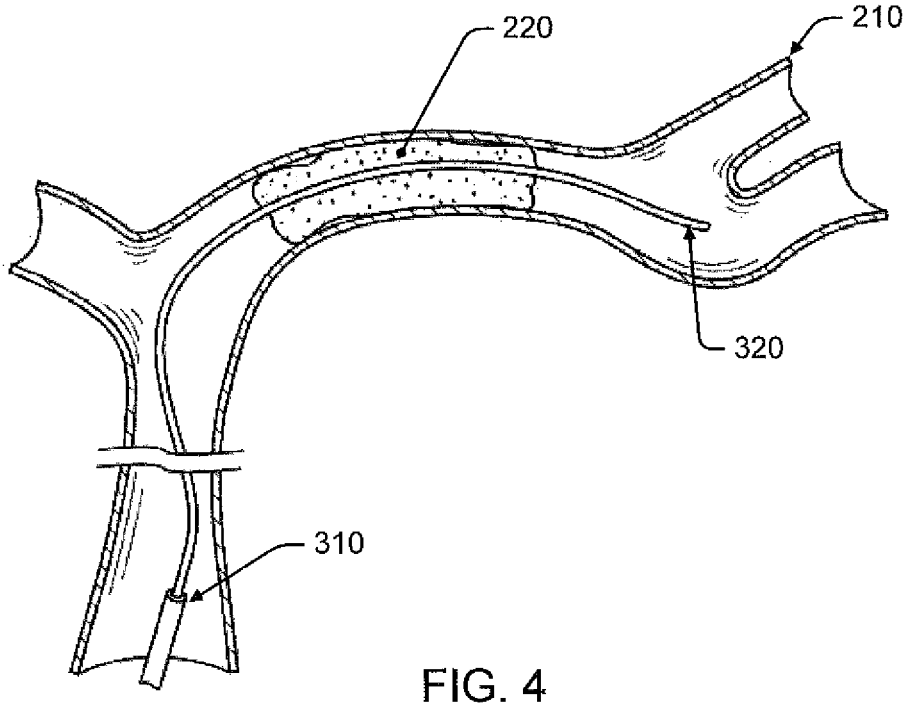


FIG. 4

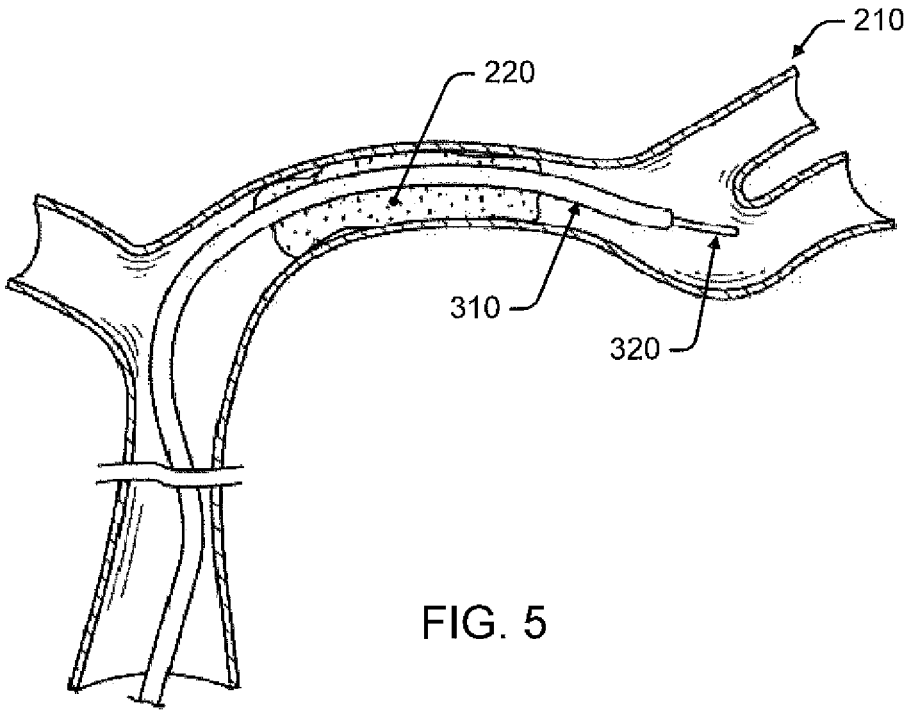


FIG. 5

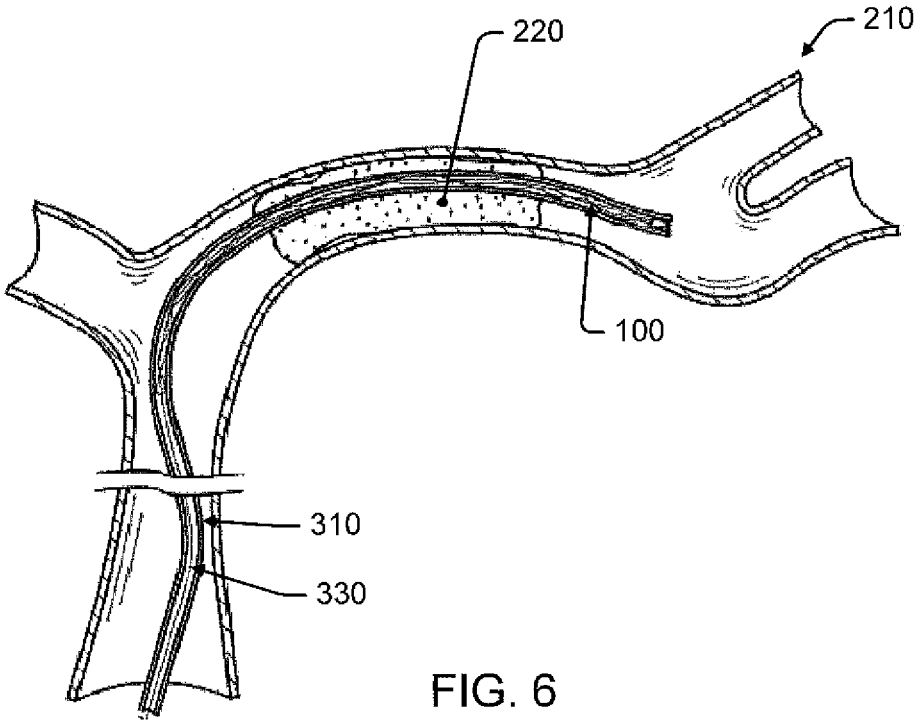


FIG. 6

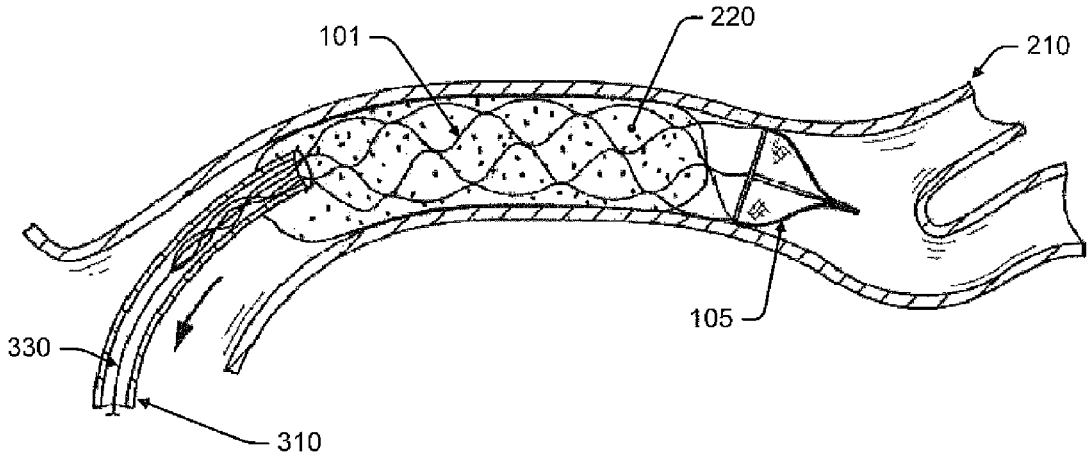


FIG. 7

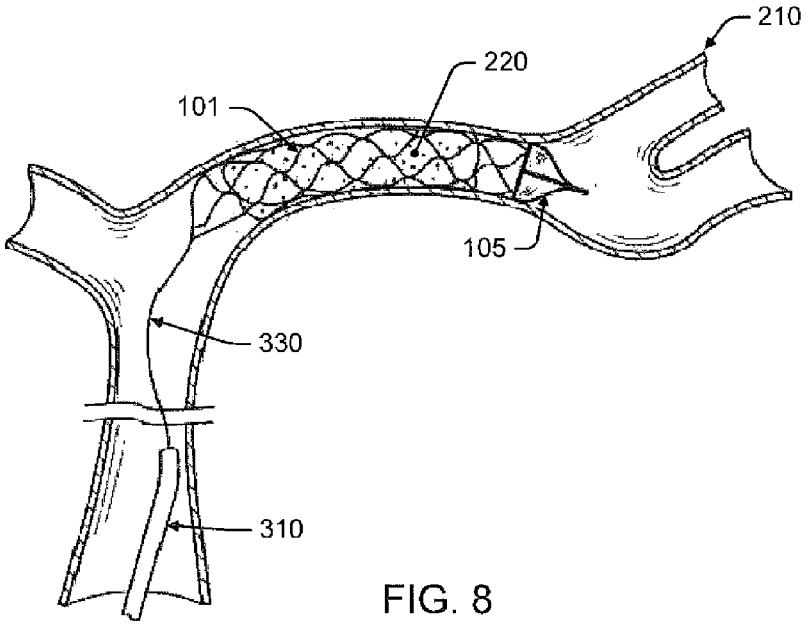


FIG. 8

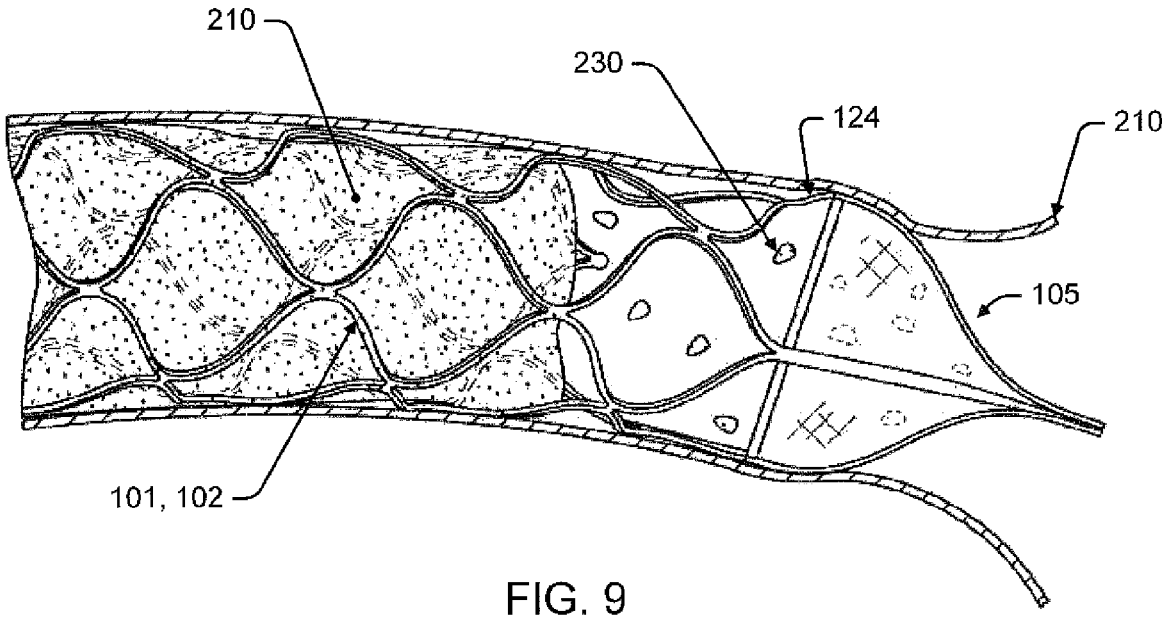


FIG. 9

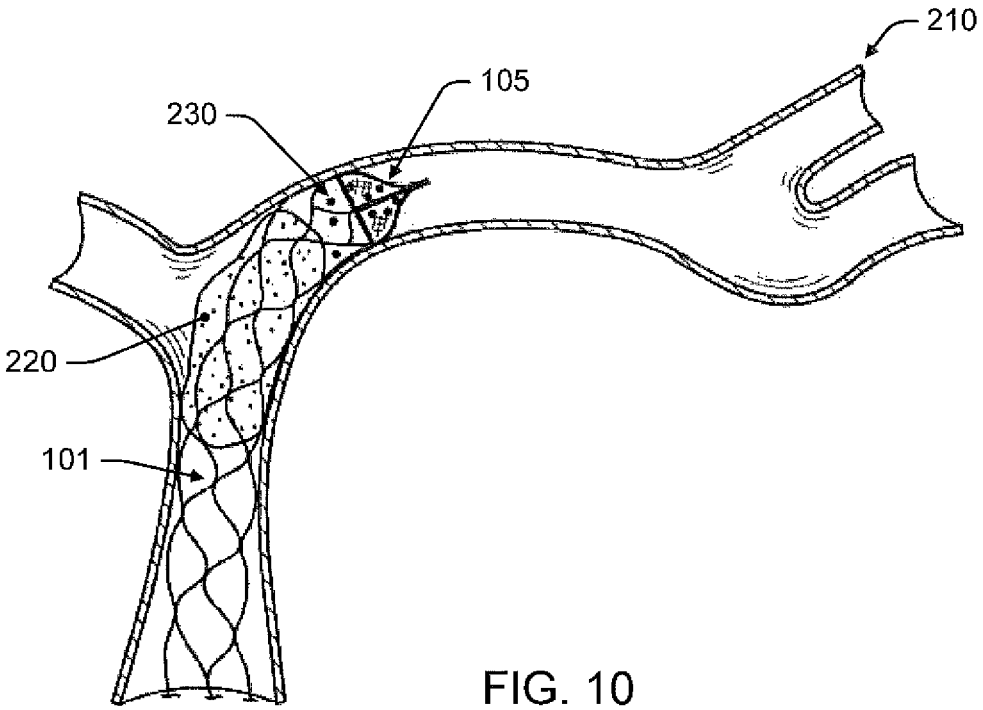


FIG. 10

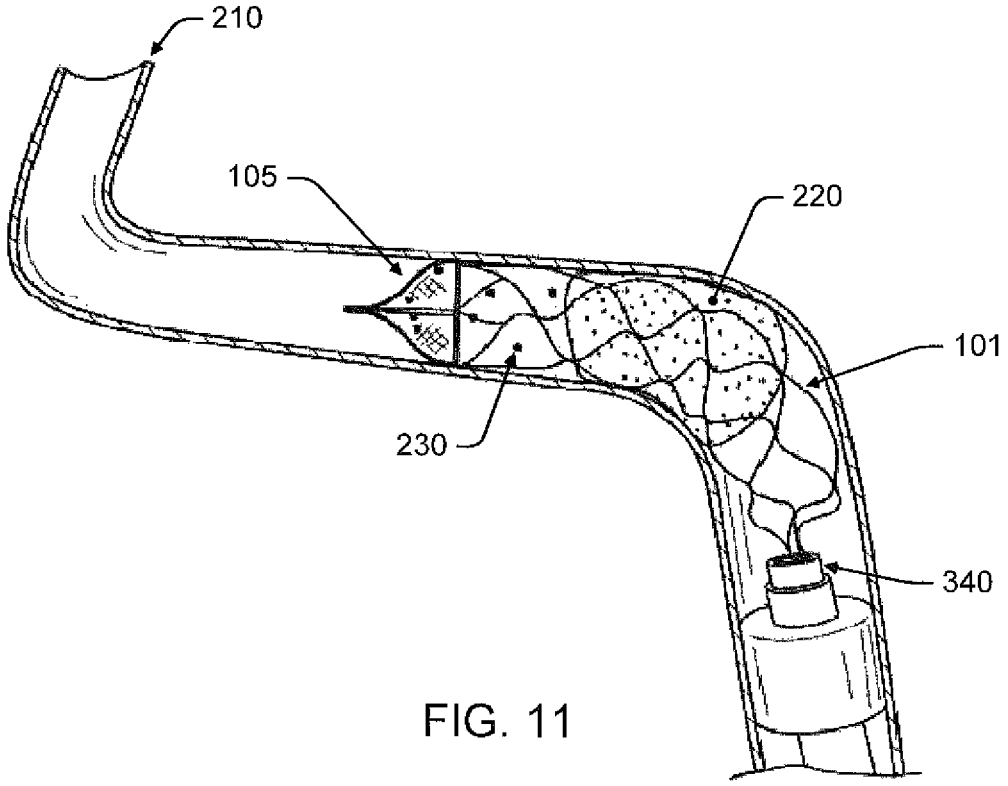


FIG. 11

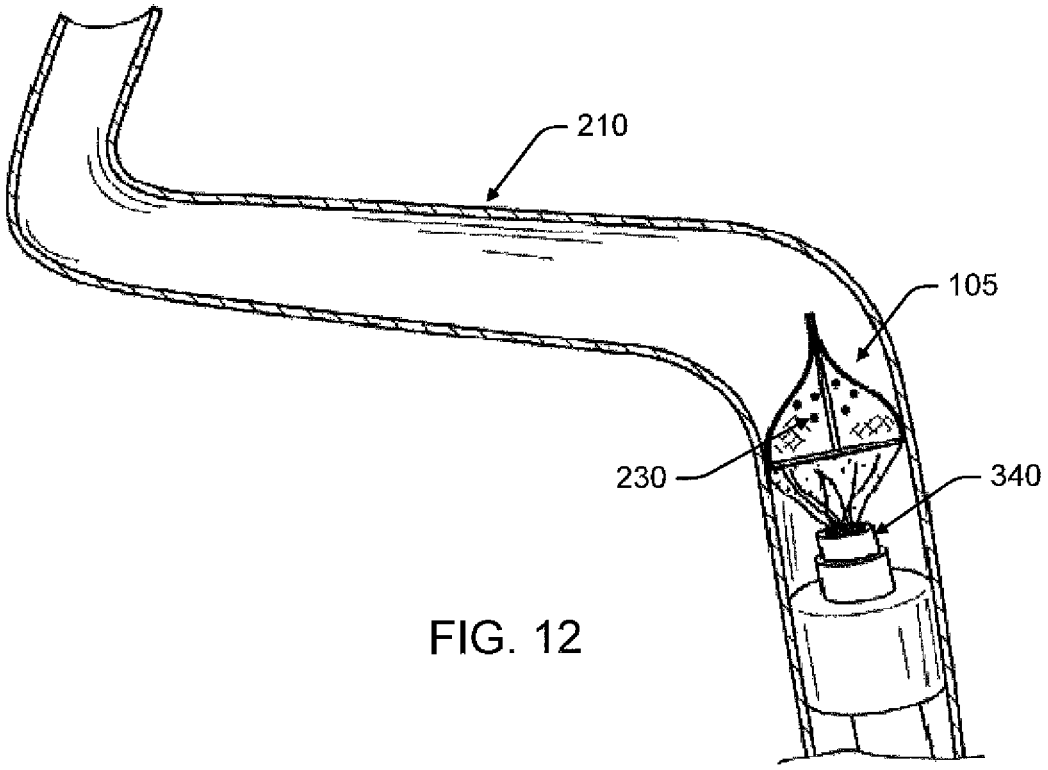


FIG. 12

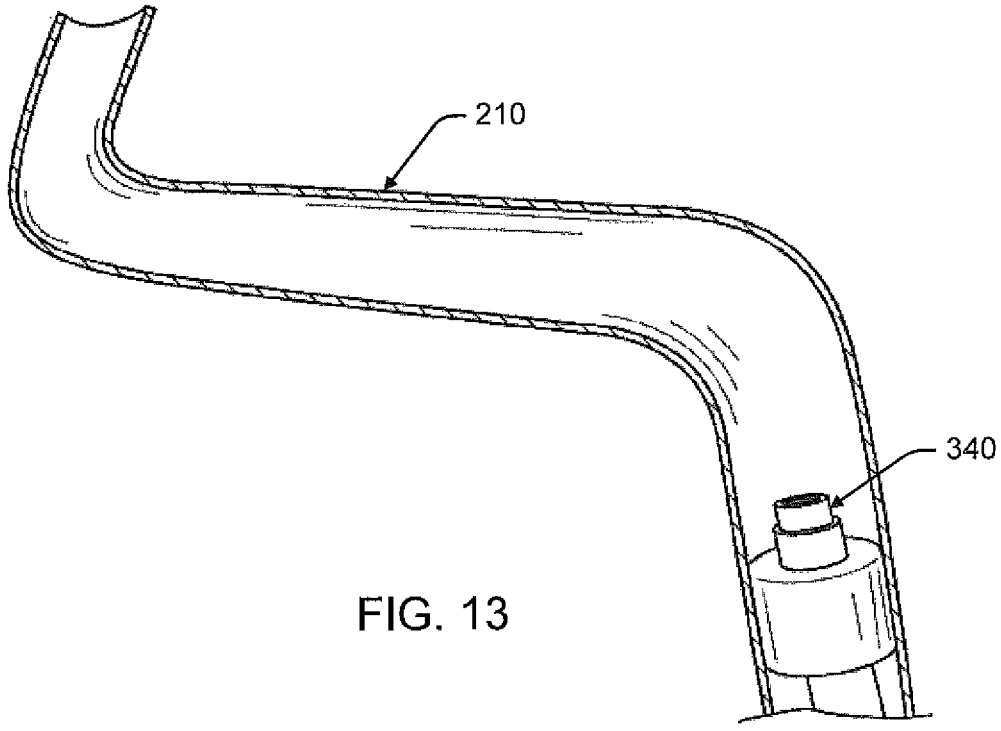


FIG. 13

THROMBECTOMY DEVICE WITH DISTAL PROTECTION

BACKGROUND

Occlusion of a blood vessel can be caused by a thrombus (i.e., blood clot) that forms in the blood vessel, or by an embolus, i.e., a blood clot that travels downstream. The blockage disrupts blood flow, which prevents oxygen and nutrients from being delivered to their intended locations. Tissue distal to a blood clot that is deprived of oxygen and nutrients can no longer function properly. For every minute that treatment is delayed, additional cellular death of critical tissue can occur.

Current technology for blood flow restoration, for example for treating cerebral arteries occluded by thrombi, can often take hours to reestablish flow in the artery, and can lead to unintended complications. Apparatus and methods for treating cerebral thrombi are often ineffective or only partially effective at resolving thrombus removal, and may result in distal embolization or embolization of uninvolved arteries. For example, some current devices are designed to pierce through a thrombus, or are designed to deploy distally to the thrombus before engaging the thrombus. These devices often fail to capture all of a thrombus, can damage vessel walls distal of a thrombus, can be difficult to maneuver, can unintentionally dislodge portions of a thrombus prior to capture, and/or can take significant amounts of time to restore blood flow. Dislodgment of portions of the thrombus, referred to as secondary emboli, often cause complications because the secondary emboli may travel downstream and occlude other vessels or arteries.

SUMMARY

The subject technology is illustrated, for example, according to various aspects described below. Various examples of aspects of the subject technology are described as numbered clauses (1, 2, 3, etc.) for convenience. These are provided as examples, and do not limit the subject technology. It is noted that any of the dependent clauses may be combined in any combination, and placed into a respective independent clause, e.g., clause 1 and 17. The other clauses can be presented in a similar manner.

1. A vascular device, comprising:
   - a frame attached to a distal end of a delivery wire, the frame comprising a cylindrical body formed of a plurality of interconnecting members, the interconnecting members being configured to exert a first radial force against an inner wall of an anatomical lumen; and
   - a protector having a proximal end, a distal end, and a profile that tapers distally from a proximal cross-sectional dimension to a reduced distal cross-sectional dimension, the protector being coupled to a distal end of the frame via a plurality of connecting members, each of the members extending from a distal end of a corresponding interconnecting member and converging distally to form a taper, the connecting members being configured to exert a second radial force, less than the first radial force, against the inner wall of the lumen.

2. The vascular device of clause 1, wherein a proximal portion of the plurality of connecting members form a greater cross-sectional dimension than does the cylindrical body.

3. The vascular device of clause 1, wherein a proximal end of the connecting members tapers proximally radially inward without converging to a central longitudinal axis of the frame.

4. The vascular device of clause 1, wherein each of the connecting members comprise a curve having a positive slope, negative slope, and an apex.

5. The vascular device of clause 4, wherein the positive and negative slopes are configured to facilitate deflection of the protector as the protector is advanced in the anatomical lumen.

6. The vascular device of clause 4, wherein the interconnecting members of the frame radially expand to a first diameter, and the connecting members radially expand to a second diameter, greater than the first diameter, wherein the second diameter is formed of apexes of each of the connecting members.

7. The vascular device of clause 1, wherein each of the connecting members comprise a pivot, the pivot having a reduced cross section that permits the protector to radially expand independent of a radial expansion of the frame.

8. The vascular device of clause 1, wherein the protector is coupled to the frame by a chain comprising a plurality of links that permit the protector to radially expand independently of a radial expansion of the frame.

9. The vascular device of clause 8, wherein the links are non-ridgidly joined to each other so that the chain is highly laterally flexible but strong in longitudinal tension.

10. The vascular device of clause 8, wherein the chain is micromachined.

11. The vascular device of clause 1, wherein the protector further comprises a mesh.

12. The vascular device of clause 11, wherein the mesh comprises a plurality of pores sized such that the mesh is configured to capture emboli without preventing blood flow past the mesh.

13. The vascular device of clause 12, wherein the plurality of pores each have a pore size of about 70-200 μm.

14. The vascular device of clause 11, wherein the protector further comprises a collapsible hoop coupled to the mesh and the plurality of connecting members and disposed substantially perpendicular to a central longitudinal axis of the frame.

15. The vascular device of clause 14, wherein the hoop is coupled to the connecting members at a radial apex of the connecting members.

16. The vascular device of clause 11; wherein each of the connecting members comprise a curvature providing a sloped surface proximal of the mesh, the sloped surface being configured to assist the protector in conforming to the inner wall of the anatomical lumen as the vascular device is advanced in the lumen.

17. A method for restricting downstream travel of secondary emboli during thrombus retrieval, the method comprising:
   - advancing a microcatheter through a distal end of a guide catheter positioned in an anatomical lumen;
   - advancing a vascular device through the microcatheter such that a distal portion of the device is located adjacent a treatment site in the lumen, the device comprising:
   - a frame attached to a distal end of a delivery wire, the frame comprising a cylindrical body formed of a plurality of interconnecting members, the interconnecting members being configured to exert a first radial force against an inner wall of the lumen; and

a protector coupled to a distal end of the frame via a plurality of connecting members, each of the members extending from a distal end of a corresponding interconnecting member and converging distally to form a taper, the connecting members being configured to exert a second radial force, less than the first radial force, against the inner wall of the lumen;

withdrawing the microcatheter relative to the device to expose the device, thereby permitting the frame to expand against a length of the thrombus and engage the thrombus;

retrieving the thrombus by moving the device relative to the guide catheter until the guide catheter covers a portion of the frame; and

restricting downstream travel of secondary emboli during the expanding of the frame and the retrieval of the thrombus by capturing the secondary emboli in the protector.

18. The method of clause 17, wherein the connecting members comprise a sloped surface that permits the protector to conform to the inner wall of the lumen as the device is moved in the lumen.

19. The method of clause 18, wherein the sloped surface comprises a curve having a positive slope, negative slope, and an apex.

20. The method of clause 17, further comprising minimizing gaps from forming between the inner wall of the lumen and the protector by radially expanding the protector to a diameter larger than a greatest diameter of the frame.

21. The method of clause 17, wherein the protector radially expands independent of the frame.

22. The method of clause 17, wherein the protector is coupled to the frame by a chain.

23. The method of clause 22, wherein the chain comprises a plurality of links that are non-ridgidly joined to each other.

24. The method of clause 17, wherein the restricting downstream travel comprises capturing the secondary emboli with a mesh attached to the protector, the mesh comprising a plurality of pores sized to capture the secondary emboli without preventing blood flow in the lumen past the protector.

25. The method of clause 17, further comprising collapsing the protector by moving the device relative to the guide catheter until the guide catheter covers a portion of the protector, wherein the guide catheter deflects the connecting members, thereby causing the protector to collapse.

It is understood that other configurations of the subject technology will become readily apparent to those skilled in the art from the following detailed description, wherein various configurations of the subject technology are shown and described by way of illustration. As will be realized, the subject technology is capable of other and different configurations and its several details are capable of modification in various other respects, all without departing from the scope of the subject technology. Accordingly, the drawings and detailed description are to be regarded as illustrative in nature and not as restrictive.

BRIEF DESCRIPTION OF THE DRAWINGS

A detailed description will be made with reference to the accompanying drawings:

FIG. **1** depicts a medical device according to some embodiments of the subject technology.

FIG. **2**A depicts a side view of a distal portion of a medical device according to some embodiments of the subject technology.

FIG. **2**B depicts a side view of a distal portion of a medical device according to some embodiments of the subject technology.

FIG. **3** depicts a cross section view of a vessel and delivery of a medical device according to some embodiments of the subject technology.

FIG. **4** depicts a cross section view of a vessel and delivery of a medical device according to some embodiments of the subject technology.

FIG. **5** depicts a cross section view of a vessel and delivery of a medical device according to some embodiments of the subject technology.

FIG. **6** depicts a cross section view of a vessel and delivery of a medical device according to some embodiments of the subject technology.

FIG. **7** depicts a cross section view of a vessel and deployment of a medical device according to some embodiments of the subject technology.

FIG. **8** depicts a cross section view of a vessel and capture of a thrombus using a medical device according to some embodiments of the subject technology.

FIG. **9** depicts a cross section view of a vessel and distal portion of a medical device capturing secondary emboli according to some embodiments of the subject technology.

FIG. **10** depicts a cross section view of a vessel and retrieval of a thrombus using a medical device according to some embodiments of the subject technology.

FIG. **11** depicts a cross section view of a vessel and retrieval of a thrombus using a medical device according to some embodiments of the subject technology.

FIG. **12** depicts a cross section view of a vessel and retrieval of a thrombus using a medical device according to some embodiments of the subject technology.

FIG. **13** depicts a cross section view of a vessel and retrieval of a thrombus using a medical device according to some embodiments of the subject technology.

DETAILED DESCRIPTION

The detailed description set forth below is intended as a description of various configurations of the subject technology and is not intended to represent the only configurations in which the subject technology may be practiced. The appended drawings are incorporated herein and constitute a part of the detailed description. The detailed description includes specific details for the purpose of providing a thorough understanding of the subject technology. However, it will be apparent to those skilled in the art that the subject technology may be practiced without these specific details. In some instances, well-known structures and components are shown in block diagram form in order to avoid obscuring the concepts of the subject technology.

Current technology for blood flow restoration, for example for treating cerebral arteries occluded by thrombi, can often take hours to reestablish flow in the artery, and can lead to unintended complications. Apparatus and methods for treating cerebral thrombi are often ineffective or only partially effective at resolving thrombus removal, and may result in distal embolization or embolization of uninvolved arteries. For example, some current devices are designed to pierce through a thrombus, or are designed to deploy distally to the thrombus before engaging the thrombus. These devices often fail to capture all of a thrombus, can damage vessel walls distal of a thrombus, can be difficult to maneuver, can unintentionally dislodge portions of a thrombus prior to capture, and/or can take significant amounts of time to restore blood flow. Dislodgment of portions of the throm-

bus, referred to as secondary emboli, often cause complications because the secondary emboli may travel downstream and occlude other vessels or arteries.

The medical devices of the subject technology solves some or all of the foregoing problems by preventing secondary emboli from traveling downstream during thrombus retrieval. The medical devices include a distal portion that is designed to capture the secondary emboli, and therefore, prevent the secondary emboli from traveling downstream during clot retrieval.

The medical device comprises a frame configured to apply a radial force against an inner wall of a lumen by utilizing various suitable means. For example, the medical device may be a self-expanding stent and/or a balloon-expandable stent. In some embodiments, "vessel" or "lumen" may refer to blood vessels (including arteries and veins) or other suitable body organs having a lumen, such as the gastrointestinal tract (e.g., esophagus, stomach, small intestine, colon, rectum), bile ducts, urinary bladder, ureter, urethra, trachea, bronchi, and the like. As will be seen below, the medical device includes a distal portion configured to capture secondary emboli during thrombus retrieval.

FIG. **1** depicts a medical device **100** according to some embodiments of the subject technology. The medical device **100** includes a frame **101** having a proximal portion **110** and a distal portion **120**. The frame comprises a cylindrical body formed of a plurality of interconnecting members **102**. The interconnecting members **102** may comprise undulating members which extend in a generally longitudinal direction. The interconnecting members **102** may be connected to each other by a plurality of joints **103**, to thereby form a substantially cylindrical shape. The joints **103** may be formed by welding, soldering, or otherwise joining the interconnecting members **102**. Alternatively, the medical device **100** may be formed, for example, by laser cutting a pre-formed tube or sheet, by interconnecting a multitude of members by laser welding, or by other suitable methods such as electrochemical etching, grinding, piercing, electroforming, or other means.

The proximal portion **110** includes a tapered section **104** extending from the frame **101** toward a proximal end **112**. The proximal end **112** includes a connection mechanism configured to attach the frame **101** to a distal end of a delivery wire. The proximal end **112** may be constructed from a radiopaque material or include a radiopaque marker allowing in vivo imaging of the medical device **100**.

The connection mechanism may include a generally non-detachable interface or transition point between the medical device **100** and the delivery wire. In some embodiments the connection mechanism may be integrally formed with the delivery wire and/or the medical device **100**. Depending on the procedure and intended use of the medical device **100**, it may be advantageous to have a connection mechanism that permits release of the medical device **100**. For example, during a blood flow restoration procedure, it may prove difficult and/or dangerous to fully retrieve a thrombus due to a complicated vasculature or the risk of damaging a lumen wall. Leaving the medical device **100** behind may prove to be the only option available to a surgeon or other medical personnel. In other circumstances the medical device **100** may include drug-eluding capabilities, and/or may be coated with a particular type of drug that facilitates thrombus dissolution. It may be advantageous in such circumstances to release the medical device **100** and allow the medical device **100** to anchor the thrombus against the lumen wall while the thrombus is dissolved by the drug.

The distal portion **120** includes a protector **105** having a proximal end **121** and a distal end **122**. The protector **105** is coupled to a distal end of the frame **101** via a plurality of connecting members **124**. For example, each of the connecting members **124** may extend from a distal end **106** of a corresponding interconnecting member **102**, and converge distally to form a taper.

The protector includes a mesh **126**. The mesh **126** is disposed between the connecting members **124**, thereby forming an area to capture emboli during clot retrieval. The mesh **126** may be coupled to the connecting members **124** with adhesive, solder, weld, or other suitable means of attachment. The mesh may comprise a plurality of pores sized such that the mesh **126** is configured to capture emboli without preventing blood from flowing through the mesh **126**. For example, the plurality of pores of the mesh **126** may each have a pore size of about 70-200 μm.

In one aspect, the protector **105** may include a collapsible hoop **128**. The hoop **128** is disposed at the proximal end **121** of the protector **105** and disposed substantially perpendicular to a central longitudinal axis of the frame **101**. The hoop **128** is coupled to the mesh **126** and the connecting members **124**. The hoop **128** may be coupled to the mesh **128** and the connecting members **124** with adhesive, solder, weld, or other suitable means of attachment. In one aspect, the hoop **128** assists in deploying the protector **105** and/or the mesh **128**, such that upon deployment, the mesh **128** is in an expanded configuration and capable of capturing emboli within the area formed by the mesh **128**. In one aspect, the hoop **128** may be coupled to the connecting members **124** at a radial apex of the connecting members **124**, as described further below.

FIG. **2**A depicts a side view of the distal portion **120** of the medical device **100**, according to some embodiments of the subject technology. The protector **105** may have a general profile that includes a taper that extends distally from a proximal cross-sectional dimension to a reduced distal cross-sectional dimension. The taper may be formed by the connecting members **124**.

In one aspect, the taper formed by the connecting members **124** may comprise a curve **134** having a positive slope, negative slope, and an apex **136**. The positive and negative slopes of the connecting members **124** may be configured to facilitate deflection of the protector **105** as the protector **105** is advanced in the anatomical lumen. For example, from the proximal end **121** of the protector **105**, each of the connecting members **124** may extend distally, radially outward, toward the apexes **136**. The portion of the connecting members **124** between the proximal end **121** and the apexes **136** have a positive slope. From the apexes **136**, each of the connecting members **124** converge distally, radially inward, toward the distal end **122**. The portion of the connecting members **124** between the apexes **136** and the distal end **122** have a negative slope. The connecting members **124** converging to the distal end **122** may be joined to one another at the distal end **122**. In another example, the connecting members **124** converging to the distal end **122** may be arranged in an overlapping configuration and be unattached to each other at the distal end **122**. By being unattached to adjacent connecting members **124** at the distal end **122**, the connecting members **124** may facilitate deployment and/or resheathing of the medical device **100** from a microcatheter by allowing the connecting members **124** to slide relative to each other at the distal end **122**.

In other words, the protector **105** may have a profile that includes a first taper that extends proximally radially inward from the apex **136** to the proximal end **121**, a cross sectional

diameter of the protector **105** at the apex **136** being larger than a cross sectional diameter of the protector **105** at the proximal end **121**. In one aspect, because the connecting members **124** taper proximally radially inward from the apexes **136** to the distal end **106** of the corresponding interconnecting member **102**, the connecting members **124** do not converge to a central longitudinal axis of the frame **101**. The profile also includes a second taper that extends distally radially inward from the apexes **136** to the distal end **122**, a cross sectional diameter of the protector **105** at the distal end **122** being smaller than the cross sectional diameter of the protector **105** at the apex **136** and the proximal end **121**.

In one aspect, because of the sloped surface created by the curvature **134** of the connecting members **124** proximal of the mesh **126**, the protector **105** may be deflected to conform to the inner wall of the anatomical lumen as the medical device **100** is advanced in the lumen. Thus, as the anatomical lumen changes in diameter, the protector **105** is deflected by the sloped surface of the connecting members **124** to reduce the diameter of the protector **105**, as discussed further below.

In one aspect, the protector **105** has a larger diameter than the frame **101** in order to prevent emboli from passing between an inner wall of the anatomical lumen and an outer surface of the protector **105**. For example, a proximal portion of the plurality of connecting members **124** may form a greater cross-sectional dimension than does the cylindrical body formed by the frame **101**. Specifically, because each of the connecting member **124** extends distally and radially outward from the distal ends **106** of the interconnecting members **102**, to the apex **136**, the protector **105** has a larger cross-sectional dimension than the cylindrical body formed by the frame **101**.

The protector **105** has its largest diameter at the apexes **136**. For example, the interconnecting members **102** of the frame **101** radially expand to a first diameter D**1**, and the connecting members **124** radially expand to a second diameter D**2**, formed of the apexes **136** of each of the connecting members **124**. The second diameter D**2** is greater than the first diameter D**1**, and is greater than all other diameters of the medical device **100**.

In another aspect, even though the connecting members **124** have a curvature **134** that forms a larger cross sectional diameter at the apexes **136**, the connecting members **124** exert a radial force against the inner wall of the anatomical lumen that is less than a radial force exerted by the interconnecting members **102** against the inner wall of the anatomical lumen. The frame **101** may be designed to generate specific forces once it is deployed and released from a microcatheter in order to optimally engage and remove a wide range of both soft and hard thrombi. By deploying the frame **101** across a thrombus, the frame **101** may self-expand to a diameter due to elastic energy stored in the interconnecting members **102**. The frame **101** may expand in the anatomical lumen until equilibrium is reached between the stored elastic energy and an opposing force from the surrounding inner wall of the anatomical lumen and/or the thrombus. The interconnecting members **102** of the medical device **100** may penetrate the thrombus, promoting adhesion and embedment of the thrombus to the frame **101**, and the expanding force of the interconnecting members **102** may promote dislodgment of the thrombus from the inner wall of the anatomical lumen.

The protector **105** may be designed to generate a force once it is deployed and released from a microcatheter, that is less than the force generated by the frame **101**. The reduced force of the protector **105** allows the protector **105** to deflect and conform to the inner wall of the anatomical lumen with less opposing force from the inner wall of the anatomical lumen. By deploying the protector **105** distal of the thrombus, the protector may self-expand to a larger diameter than the frame, due to elastic energy stored in the connecting members **124**. The protector **105** may expand in the anatomical lumen until equilibrium is reached between the stored elastic energy and an opposing force from the surrounding inner wall of the anatomical lumen.

For example, the stored elastic energy of the frame **101** and the protector **105** may generate an outward force known as a radial force. The radial force is equivalent to the outward force exerted by the frame **101** or the protector **105** during compression. In some aspects, the radial force of the frame **101** may be designed so that it is high enough to resist compression forces from the surrounding inner wall of the anatomical lumen, maintain patency of the frame **101**, and restore flow through the thrombus site. The radial force of the protector **105** may be designed so that it is less than the radial force of the frame, such that compression forces from the surrounding inner wall of the anatomical lumen cause the protector to deform and conform to the inner wall of the anatomical lumen.

The frame **101** may have a radial force measurement greater than or equal to 0.0010 N per mm of length of the portion of the frame **101** that is configured to contact the inner wall of the anatomical lumen or the thrombus. The protector **105** may have a radial force measurement in a range of about 0.0006-0.0009 N per mm of length of the portion of the protector **105** that is configured to contact the inner wall of the anatomical lumen. In another example, the radial force measurement may be less than 0.0006 N per mm or be in a range of about 0.0009-0.0010 N per mm. The length in this unit refers to a proximal to distal direction measurement.

In another aspect, the protector **105** may radially expand independent of a radial expansion of the frame **101**. For example, the connecting members **124** may comprise a pivot **132** having a reduced cross section that permits the protector **105** to radially expand independent of the radial expansion of the frame **101**. The reduced cross section of the pivot **132** is prone to bend and deflect, thereby allowing the protector **105** to radially expand independent of the frame **101**.

Referring to FIG. **2**B, the protector **105** may be coupled to the frame **101** by a chain **144** comprising a plurality of links that permit the protector **105** to radially expand independently of the radial expansion of the frame **101**. The links of the chain **144** are non-ridgidly joined to each other so that the chain is highly laterally flexible but strong in longitudinal tension. In one aspect, the chain **144** is micromachined. The chain **144** may extend from the distal end **106** of the interconnecting members **102** to the proximal end of the mesh **126**. Each chain **144** may comprise two individual rows, each row coupled to the other via a chain link disposed substantially at a center portion of the row. The chain **144** may be coupled to the distal end **106** of the interconnecting members **102** and the proximal end of the mesh **126** by adhesive, weld, solder, fasteners, or other suitable means for attachment.

Radiopaque markers may be located adjacent the proximal or distal ends **112**, **122** or both, and may be located at any position along the length of the medical device **100** between the proximal and distal ends **112**, **122**. The markers may be attached to the medical device **100** by techniques such as adhesives, heat fusion, interference fit, fasteners, intermediate members, coatings, or by other techniques.

In some embodiments, the markers are comprised of ultrasonic markers, MRI safe markers, or other markers. In some embodiments ultrasonic markers permit a physician to accurately determine the position of the medical device **100** within a patient under ultrasonic visualization. Materials for an ultrasonic marker have an acoustical density sufficiently different from the medical device **100** to provide suitable visualization via ultrasonic techniques. Exemplary materials comprise polymers, metals such as tantalum, platinum, gold, tungsten and alloys of such metals, hollow glass spheres or microspheres, and other materials.

In some embodiments, MRI safe markers permit a physician to accurately determine the position of the medical device **100** within a patient under magnetic resonance imaging. Exemplary materials for making MRI safe marker have a magnetic signature sufficiently different from the medical device **100** to provide suitable visualization via MRI techniques. Exemplary materials comprise polymers, metals such as tantalum, platinum, gold, tungsten and alloys of such metals, non-ferrous materials, and other materials.

A technique for engaging and removing a thrombus **220** and restricting downstream travel of secondary emboli during thrombus retrieval will now be discussed with reference to FIGS. **3-13**. Referring to FIG. **3**, the medical device **100** may be inserted into an anatomical lumen **210** by first inserting a guide wire **320** into the anatomical lumen **210**. The guide wire **320** is advanced through a guide catheter and a microcatheter **310** to the treatment site, adjacent the thrombus **220**. Referring to FIG. **4**, the guide wire **320** is advanced distally through the thrombus **220**. Once in position, the microcatheter **310** is advanced over the guide wire **320**, through a distal end of the guide catheter, into the anatomical lumen **210**. Referring to FIG. **5**, the microcatheter **310** is advanced distally through the thrombus **220**. The guide wire **320** is then withdrawn proximally.

Referring to FIG. **6**, the medical device **100** is advanced through the microcatheter **310** such that the distal portion **120** of the medical device **100** is disposed distal of the thrombus **220** in the anatomical lumen **210**. The medical device **100** is advanced through the microcatheter **310** by a pusher or delivery wire **330** that is coupled to the proximal end of the medical device **100**. The microcatheter **310** compresses the medical device **100** and thus, maintains the medical device in a compressed configuration as the medical device **100** is advanced to the treatment site.

Referring to FIGS. **7** and **8**, the microcatheter **310** is withdrawn proximally relative to the medical device **100** to expose the medical device **100**, thereby permitting the protector **105** and the frame **101** to expand. The frame **101** expands against a length of the thrombus **220** and engages the thrombus **220**. As discussed above, the frame **101** is designed to engage and remove thrombi that are both generally soft, or malleable, or generally hard, or callous. The protector **105** expands against the inner wall of the anatomical lumen. During expansion of the frame **101**, the protector **105** restricts downstream travel of any dislodged portions of the thrombus **220**, referred to as secondary emboli **230**, by capturing the secondary emboli in the protector **105**.

Referring to FIGS. **9** and **10**, the medical device **100** is withdrawn proximally, along with the thrombus **220**. During retrieval of the thrombus **220**, dislodgment of portions of the thrombus **220**, referred to as secondary emboli **230**, are captured by the protector **105**, thereby preventing the secondary emboli **230** from traveling downstream and occluding other vessels or arteries. In one aspect, the probability of gaps forming between the protector **105** and the inner surface of the anatomical lumen **210** are minimized because the protector **105** is configured to independently radially expand to a diameter larger than a greatest diameter of the frame **101**. Accordingly, the protector **105** captures the majority, if not all, of the secondary emboli **230**.

As the medical device **100** is withdrawn proximally within the anatomical lumen **210**, the sloped surface of the connecting members **124** deflect the protector **105** so that the protector **105** conforms to the inner wall of the anatomical lumen **210**.

Referring to FIG. **11**, the medical device **100** is withdrawn proximally to the guide catheter **340**. The guide catheter **340** causes the frame to collapse, with the thrombus **220** engaged therein. The thrombus **220** is thus retrieved and removed from the anatomical lumen **210**. Referring to FIGS. **12** and **13**, the medical device **100** is further proximally withdrawn such that the protector **105** is collapsed by the guide catheter **340**, with the secondary emboli **230** captured therein. Proximally withdrawing the medical device **100** into the guide catheter **340** causes the frame **101** to collapse due to deflection of the interconnecting members **102** by the guide catheter **340**. Likewise, movement of the medical device **100** into the guide catheter **340** causes the protector **105** to collapse due to deflection of the connecting members **124** by the guide catheter **340**.

In one arrangement, the medical device **100** may be comprised of metal, polymer, ceramic, permanent enduring materials, and may comprise either of or both of non-bioabsorbable and bioabsorbable materials. Exemplary materials include, but are not limited to, NITINOL®, stainless steel, cobalt chromium alloys, Elgiloy, magnesium alloys, polylactic acid, poly glycolic acid, poly ester amide (PEA), poly ester urethane (PEU), amino acid based bio-analogous polymers, tungsten, tantalum, platinum, polymers, bio-polymers, ceramics, bio-ceramics, or metallic glasses. Part or all of the medical device may elute over time substances such as drugs, biologics, gene therapies, anti-thrombotics, coagulants, anti-inflammatory drugs, immuno-modulator drugs, anti-proliferatives, migration inhibitors, extracellular matrix modulators, healing promoters, re-endothelialization promoters, or other materials. In some embodiments, the medical device **100** may be formed from materials having shape memory properties. In some embodiments, the medical device **100** may be finished by processes to remove slag. In some embodiments, the medical device **100** may be subjected to a tempering treatment at temperatures customarily applied to the material so that the impressed structure is permanently established.

The medical device **100** may have various lengths and diameters. For example, the medical device **100** may have specific cross-sectional diameters, the diameters being measured when the medical device **100** is fully free to expand, ranging from about 2 mm to about 6 mm. If the medical device **100** has a diameter between 3 mm and 4 mm, it may be used in a size 18 microcatheters (i.e., microcatheters with an inner diameter of approximately 0.21 inch). If the medical device **100** has a diameter between 5 mm and 6 mm, it may be used in a size 27 microcatheters (i.e., microcatheters with an inner diameter of approximately 0.027 inch). However, other suitable cross-sectional diameters may be used without deviating from the scope of the subject technology. In some embodiments, the medical device **100** may have lengths, measured proximally to distally along the longitudinal axis of the medical device **100**, ranging from 15 min to 40 mm, though other ranges and sizes are also possible.

Skilled artisans may implement the described functionality in varying ways for each particular application. Various

components and blocks may be arranged differently (for example, arranged in a different order, or partitioned in a different way) all without departing from the scope of the subject technology. It is understood that the specific order or hierarchy of steps in the processes disclosed is an illustration of exemplary approaches. Based upon design preferences, it is understood that the specific order or hierarchy of steps in the processes may be rearranged. Some of the steps may be performed simultaneously. The accompanying method claims present elements of the various steps in a sample order, and are not meant to be limited to the specific order or hierarchy presented.

The previous description is provided to enable any person skilled in the art to practice the various aspects described herein. The previous description provides various examples of the subject technology, and the subject technology is not limited to these examples. Various modifications to these aspects will be readily apparent to those skilled in the art, and the generic principles defined herein may be applied to other aspects. Thus, the claims are not intended to be limited to the aspects shown herein, but is to be accorded the full scope consistent with the language claims, wherein reference to an element in the singular is not intended to mean "one and only one" unless specifically so stated, but rather "one or more." Unless specifically stated otherwise, the term "some" refers to one or more. Pronouns in the masculine (for example, his) include the feminine and neuter gender (for example, her and its) and vice versa. Headings and subheadings, if any, are used for convenience only and do not limit the invention.

A phrase such as an "aspect" does not imply that such aspect is essential to the subject technology or that such aspect applies to all configurations of the subject technology. A disclosure relating to an aspect may apply to all configurations, or one or more configurations. An aspect may provide one or more examples. A phrase such as an aspect may refer to one or more aspects and vice versa. A phrase such as an "aspect" does not imply that such aspect is essential to the subject technology or that such aspect applies to all configurations of the subject technology. A disclosure relating to an aspect may apply to all aspects, or one or more aspects. An aspect may provide one or more examples. A phrase such as an "aspect" may refer to one or more aspects and vice versa. A phrase such as a "configuration" does not imply that such configuration is essential to the subject technology or that such configuration applies to all configurations of the subject technology. A disclosure relating to a configuration may apply to all configurations, or one or more configurations. A configuration may provide one or more examples. A phrase such as a "configuration" may refer to one or more configurations and vice versa.

The word "exemplary" is used herein to mean "serving as an example or illustration." Any aspect or design described herein as "exemplary" is not necessarily to be construed as preferred or advantageous over other aspects or designs.

All structural and functional equivalents to the elements of the various aspects described throughout this disclosure that are known or later come to be known to those of ordinary skill in the art are expressly incorporated herein by reference and are intended to be encompassed by the claims. Moreover, nothing disclosed herein is intended to be dedicated to the public regardless of whether such disclosure is explicitly recited in the claims. No claim element is to be construed under the provisions of 35 U.S.C. §112, sixth paragraph, unless the element is expressly recited using the phrase "means for" or, in the case of a method claim, the element is recited using the phrase "step for." Furthermore, to the extent that the term "include," "have," or the like is used in the description or the claims, such term is intended to be inclusive in a manner similar to the term "comprise" as "comprise" is interpreted when employed as a transitional word in a claim.

What is claimed is:

1. A vascular device, comprising:

a frame attached to a distal end of a delivery wire, the frame comprising a cylindrical body formed of a plurality of interconnecting members, the interconnecting members being configured to exert a first radial force against an inner wall of an anatomical lumen when the frame has a first diameter; and

a protector having a proximal end, a distal end, and a profile that tapers distally from a proximal cross-sectional dimension to a reduced distal cross-sectional dimension, the protector being coupled to a distal end of the frame via a plurality of connecting members, each of the connecting members extending from a distal end of a corresponding interconnecting member and converging distally to form a taper, each connecting member comprising a proximal segment and a distal segment, the proximal segment of each connecting member comprising one of (a) a cross section less than that of the distal segment of the corresponding connecting member or (b) a chain comprising a plurality of links and two individual rows coupled to each other, the proximal segments permitting the protector to radially expand independent of a radial expansion of the frame, the distal segments of the connecting members being configured to exert a second radial force, less than the first radial force, against the inner wall of the lumen when the protector has the first diameter.

2. The vascular device of claim **1**, wherein a proximal portion of the plurality of connecting members form a greater cross-sectional dimension than does the cylindrical body.

3. The vascular device of claim **1**, wherein a proximal end of the connecting members tapers proximally radially inward without converging to a central longitudinal axis of the frame.

4. The vascular device of claim **1**, wherein each of the connecting members comprise a curve having a positive slope, negative slope, and an apex.

5. The vascular device of claim **4**, wherein the positive and negative slopes are configured to facilitate deflection of the protector as the protector is advanced in the anatomical lumen.

6. The vascular device of claim **4**, wherein, in an absence of external forces, the interconnecting members of the frame radially expand to a second diameter, and the connecting members radially expand to a third diameter, greater than the second diameter, wherein the third diameter is formed of apexes of each of the connecting members.

7. The vascular device of claim **1**, wherein at least one proximal segment comprises (b), and the links are non-ridgidly joined to each other so that the chain is highly laterally flexible but strong in longitudinal tension.

8. The vascular device of claim **1**, wherein at least one proximal segment comprises (b), and the chain is micromachined.

9. The vascular device of claim **1**, wherein the protector further comprises a mesh.

10. The vascular device of claim **9**, wherein the mesh comprises a plurality of pores sized such that the mesh is configured to capture emboli without preventing blood flow past the mesh.

11. The vascular device of claim 10, wherein the plurality of pores each have a pore size of about 70-200 μm.

12. The vascular device of claim 9, wherein the protector further comprises a collapsible hoop coupled to the mesh and the plurality of connecting members and disposed substantially perpendicular to a central longitudinal axis of the frame.

13. The vascular device of claim 12, wherein the hoop is coupled to the connecting members at a radial apex of the connecting members.

14. The vascular device of claim 9, wherein each of the connecting members comprise a curvature providing a sloped surface proximal of the mesh, the sloped surface being configured to assist the protector in conforming to the inner wall of the anatomical lumen as the vascular device is advanced in the lumen.

15. A vascular device, comprising:

a frame attached to a distal end of a delivery wire, the frame comprising a cylindrical body formed of a plurality of interconnecting members, the interconnecting members being configured to exert a first radial force against an inner wall of an anatomical lumen when the frame has a first diameter; and

a protector having a proximal end, a distal end, and a profile that tapers distally from a proximal cross-sectional dimension to a reduced distal cross-sectional dimension, the protector being coupled to a distal end of the frame via a plurality of connecting members, each of the connecting members extending distally from the frame, each connecting member comprising a proximal segment and a distal segment, the proximal segment of each connecting member comprising a cross section less than that of the distal segment of the corresponding connecting member, the distal segments of the connecting members being configured to exert a second radial force, less than the first radial force, against the inner wall of the lumen when the protector has the first diameter.

16. The vascular device of claim 15, wherein a proximal portion of the plurality of connecting members form a greater cross-sectional dimension than does the cylindrical body.

17. The vascular device of claim 15, wherein a proximal end of the connecting members tapers proximally radially inward without converging to a central longitudinal axis of the frame.

18. The vascular device of claim 15, wherein each of the connecting members comprise a curve having a positive slope, negative slope, and an apex.

19. The vascular device of claim 18, wherein, in an absence of external forces, the interconnecting members of the frame radially expand to a second diameter, and the connecting members radially expand to a third diameter, greater than the second diameter, wherein the third diameter is formed of apexes of each of the connecting members.

20. The vascular device of claim 15, wherein the protector further comprises a mesh.

21. The vascular device of claim 20, wherein the mesh comprises a plurality of pores sized such that the mesh is configured to capture emboli without preventing blood flow past the mesh.

22. The vascular device of claim 21, wherein the plurality of pores each have a pore size of about 70-200 nm.

23. The vascular device of claim 20, wherein the protector further comprises a collapsible hoop coupled to the mesh and the plurality of connecting members and disposed substantially perpendicular to a central longitudinal axis of the frame.

24. The vascular device of claim 23, wherein the hoop is coupled to the connecting members at a radial apex of the connecting members.

* * * * *